REMARKS

Reconsideration of the application is respectfully requested. The references cited below are provided in a Supplementary Information Disclosure Statement, which is being submitted concurrently to this amendment.

1. The Examiner has rejected Claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Painter *et al.* (Cereal Foods World) or Wolf *et al.* US 2004/0197380 A1 or Gilles *et al.* (6,248,375) and Wilbert (5,776,887).

The Applicant respectfully traverses. Claim 1 is an independent claim and Claims 8-16 depend from claim 1.

Applicant presents affidavit of the inventors Saul Katz and Valerie Price, attesting to the fact that the present invention was conceived well before the publication date of the Painter article, and before the first filing date for either the Wolf or Gilles patent references. Therefore, none of those references is relevant to the present application under 35 USC 103.

With respect to the Wibert Patent (US 5,776,887), the Applicant submits that Wibert Patent discloses nutritional food bars for diabetics, which are prepared by combining three components of carbohydrates. Please note that there is no explicit teaching in Wibert that the nutritional composition has a low GI, only that it results in a sustained release without excessive glucose peaks. As GI is calculated as "area under the curve" or AUC on blood glucose graph over time, a sustained release is not necessarily the same as low glycemic index.

The three carbohydrate components indicate that Wibert intended a product with sustained release of glucose, or in other words a relatively flat curve in the blood glucose graph. The first component is a rapidly absorbed carbohydrate which is intended to quickly boosts blood glucose level. The preferred embodiment in Wibert is sucrose. The second and third components are

moderate absorbing and slow absorbing carbohydrates, to provide continual release of glucose over time.

Therefore, Wibert does not teach a low GI product, as is required by claim 1. Wibert teaches a sustained GI product, which is not necessarily the same thing. The presence of sucrose in the Wibert product indicates that is not necessarily a low GI product. There is no clinical validation of the GI of the Wibert product. Adding the GI numbers of the ingredients is only an approximate method for determining GI, and may be very inaccurate. It is necessary to measure the AUC using standard protocols for an accurate measure.

Absence of Sucrose

The presence of sucrose, or a rapidly absorbed carbohydrate, is a significant difference between Wibert and the present invention. There is no such ingredient in the food item which is described or claimed in the present application. Accordingly, new claim 8 excludes "rapidly absorbed" carbohydrates. One skilled in the art would understand "rapidly absorbed" to mean glucose and disaccharides which contribute directly to elevation in blood glucose, eg. maltose and sucrose (see Wibert, column 2, lines 16-18). Support for this amendment may be found in the Example described in paragraphs [40] to [62], which does not include a rapidly absorbed carbohydrate.

Sucrose, glucose and other sugars play very distinct roles in the body and the differences in relation to GI and glycemic responses as compared to fructose have been shown clinically (Wolever and Brand Miller, 1995). The glycemic response differs upon consumption of a rapidly available source of glucose (sucrose or glucose) versus a moderately or slowly absorbed source (fructose) of carbohydrate (Englyst et al. 1999; Wolever and Brand Miller, 1995).

Absence of Starch, Inclusion of Inulin

There is also an important difference in the use of non-digestible carbohydrates in the present application, and the Wibert reference. In Wibert, the "slowly absorbed" fraction must contain raw corn starch (see column 3, lines 19-20) if it is a liquid, or a high amylose corn starch, which is another slowly absorbed polysaccharide. High amylose corn starch is stated to have a GI less than 80 (as compared to the claimed upper GI value in the present invention of about 71). The slowly absorbed polysaccharide in Wibert is defined as comprising glucose units (see column 2, line 28).

In either event, the claimed invention in new claim 9 does not include corn starch as a carbohydrate ingredient, but rather includes inulin as a non-digestible oligosaccharide. Inulin is a soluble fructose polymer (see Boeckner et al, "Inulin: A Review..."), in contrast to corn starch, which is an insoluble glucose polymer. Corn starch is susceptible to amylases, which may cause blood sugar to rise. Support for new claim 9 may be found in the Example described in paragraphs [40] to [62], which does not include a starch, but does include inulin.

Research has shown that several structural and chemical differences exist between inulin and resistant starch which affect the metabolic and physiological reaction in the body upon consumption of each. The important distinctions have been outlined below.

Inulin is soluble in water. It reaches the colon essentially as an intact molecule acting as a prebiotic. Its physiological role is mediated through its prebiotic property – that is promoted through fermentation via the colonic synthesis of microflora (i.e. bifidobacteria and lactobacilli), which produces short chain fatty acids (i.e. propionic acid, butyric acid and acetic acid). These fatty acids, following their colonic absorption, are known to decrease serum cholesterol levels by reducing hepatic cholesterol synthesis through inhibiting HMG-CoA reductase activity (Mazur et al. 1990; Kim and Shin, 1998; Trautwein et al. 1998). According to many in vivo and in vitro studies, inulin also has the capacity to lower triglycerides via a reduction in de novo fatty acid synthesis in the liver through inhibiting all lipogenic enzymes (Delzenne and Kok, 1999). In addition to cholesterol and

triglycerides, inulin has been reported to lower serum levels of glucose and insulin (Kim and Shin, 1996), both known to regulate lipogenesis. The inulin-mediated decreases in glucose and insulin levels have been suggested to contribute to the reduction of hepatic fatty acid and triglyceride synthesis, and are part of the mechanism of the hypolipidemic effect of inulin (Kok et al, 1998). In isolation, short chain fatty acids have been known to have effects on adipose tissue lipolysis (Akanji et al, 1989), hepatic gluconeogenesis (Anderson and Bridges, 1984), and insulin secretion (Sasaki et al, 1977).

In summary, inulin seems to have both hypoglycemic and hypolipidemic effects – not only because of its influence on the absorption in the small intestine, in essence, but also due to its systemic effects, which are potentiated by short chain fatty acids, that are produced by its colonic fermentation. The short chain fatty acids produced via colonic fermentation of inulin also reduce colonic pH, increasing the solubility of minerals (such as Ca, Mg, and Fe), which in turn helps their absorption by passive diffusion (Kashimura et al. 1996; Ohta et al. 1995). In relation to diabetes, the health benefits of inulin go beyond its effect on serum lipid and glucose levels (Ohta et al. 1994). Thus, magnesium deficiency increases the risk of diabetes, and inulin helps increase colonic magnesium absorption.

In comparison, resistant starch (RS) is a non-viscous insoluble fiber that is resistant to enzymatic digestion in the small intestine. The ultimate health potential of RS appears to be similar to inulin, except that due to the insolubility of RS, its fermentation in the body is relatively slower and long-lasting than inulin.

Significance of High Carbohydrate Content

Claims 1, 10 and 11 each specify a high carbohydrate content. The significance of each claimed level is that it becomes more difficult to maintain a lower GI as carbohydrate content of a mixed food product goes up. As stated in the specification, in the prior art, lower GI was obtained by increasing the protein or fat portion of a food product. Thus, it is counter-intuitive to maintain or

raise the carbohydrate content while also maintaining or reducing low GI. Thus, the exemplary formulation has 56% carbohydrate while having a GI of less than about 33. Such a mixed food product did not exist in the prior art. The Balance® Bar referenced in the patent specification is representative of the prior art, where a low glycemic index was achieved by maintaining carbohydrates below 50%, and in fact below 45%.

The Significance of GI Testing

The Wibert reference does not disclose any level of glycemic index testing. The present application discusses the method of GI testing used to test the low glycemic bar, where the testing was conducted, and how the testing was done. The Glycaemic Institute in Toronto was the accredited facility which tested the low glycemic bar using the protocol endorsed by several world-leading laboratories as well as the top scientific researchers in the field of carbohydrates in human nutrition and GI (FAO, 1997). The testing resulted in a final GI of 23.6 +/- 2.7 on the glucose standard, which is considered to be very low on the glycemic index scale (low GI = 55 and below, medium GI = 56-69, high GI = 70 and above).

Clinically validating and testing the GI of food products is of paramount importance and the primary reason for the inception of the GI was to help diabetics manage their blood sugar throughout the day (Jenkins et al. 1981). Work prior had suggested that the carbohydrate exchange lists being used to regulate the diets of many diabetics for over three decades may not have reflected the physiological effect of foods. More recent clinical work has shown the coingestion of protein or fat as having an influence on the glycemic response to carbohydrate, in both normal and diabetic subjects (Gulliford et al. 1989).

As indicated in the attached article "Different Glycemic Indexes of Breakfast Cereals are Not Due to Glucose Entry into Blood But to Glucose Removal by Tissue", Schenk et al., Am J Clin Nutr 2003;78:742-8 (the "Schenk article"), there is no direct relationship between glycemic index and entry of glucose into blood. As the Schenk article demonstrates, two different cereals were tested,

one with a known low GI, the other with a higher GI. As stated on page 745, "[s]imply, BC has a low GI because of a more rapid insulin-mediated increase in tissue glucose uptake attenuates the increase in blood glucose concentration, despite a similar rate of glucose entry into the blood." The Wibert patent teaches that a nutritional composition which has controlled amounts of differently absorbed carbohydrate components. However, one skilled in the art, based on the Schenk article would know that different carbohydrate components may still result in similar blood glucose uptake, but that carbohydrate composition does not by itself determine lower GI.

It is also a significant to differentiate the influence food intake has in relation to normal subjects versus subjects with pathological disorders such as diabetes. The Wibert product is specifically targeted at diabetics. The present application is intended for any person who wishes to have a processed, ready-to-eat food item with a low glycemic index. Persons with diabetes can take much longer to dispose of the postprandial glucose versus normal subjects and may require much longer for their blood glucose to return to normal concentrations, if at all (Pi-Sunyer, 2002). The low glycemic bar of the present invention is designed primarily for normal populations with the objective of using it as a snack bar to sustain blood glucose levels in normal subjects throughout the day. In contrast, the Wibert patent describes a "nutritional composition for use by diabetics which results in a controlled or sustained absorption of carbohydrate during digestion".

The Wibert patent specifies that consumption of the products will result in a controlled or sustained absorption of carbohydrate thereby avoiding excessive blood peaks. However, this was not clinically proven as their formulations/products were not tested to determine the Glycemic Index values in humans. GI numbers of the ingredients contained in the product cannot be simply added together to determine the final GI (Pi-Sunyer, 2002). This is only an approximate method for determining the GI and several variables can affect the final GI value of a product in relation to the individual ingredients being combined together to make the final product.

For example, the literature demonstrates the following:

1. Deciphering among the numerous published GI values for ingredients and individual food items. Using published GI values for ingredients to "predict" the final GI raises a number of questions. Published GI values and tables are only as good as the source from which they originated and several considerations must be taken into account. Most tables often contain more than one GI value for the same or similar food and these values vary. For example, in the Foster-Powell table there are 29 GI values for potato and this does not include mashed potato or sweet potato, which are separate items.

2. Considering the testing method that was used to determine the GI.
    a) There are differences and different degrees of variability in capillary vs. venous blood testing. Capillary blood is preferred because it is easier to obtain and the rise in blood glucose is greater than venous plasma glucose. Thus, differences between foods are larger and easier to detect statistically using capillary blood glucose (Wolever et al, 1996). The protocol used to test the low glycemic bar used capillary blood to test the GI value.
    b) Was the testing method internationally recognized; as by the WHO/FAO (FAO, 1997)?
    c) Did the testing utilize an adequate number of subjects (6 or more) (FAO, 1997)?
    d) How tightly controlled was the testing (Wolever et al. 1991; FAO, 1997)?
    e) Was same-subject variability considered in the calculation (Wolever et al. 1989)?

3. Synergisms among the macronutrient blend of ingredients. Clinical work has shown that the coingestion of protein or fat is known to influence the glycemic response to carbohydrate (Gulliford et al. 1989).

4. Varietal differences in crop and ingredient sources. Rice is a good example of a staple food that elicits varietal differences. While digestible carbohydrate contents do not differ significantly, there is significance in the glycemic indices (Hettiarachchi et al. 2001). Carrot is also a good example of varietal differences in crops. Yearly crop seasons can yield carrots with varying dietary fiber content. While the percentage of digestible carbohydrates is similar, carrots with higher viscous fiber content will lower the glycemic response when incorporated into a mixed meal (Gustafsson et al. 1995).

5. Degree of ripeness/maturity (i.e. as fruits ripen, such as bananas, the starches will be converted to sugars (Pi-Sunyer 2002), thereby increasing the GI value. In the Foster-Powell table of GI values, an under-ripe banana can have a GI of 30, whereas an over-ripe banana can have a GI value as high as 52.

6. Composition of amylose vs. amylopectin ratios in carbohydrate or fiber sources. It has been shown that the higher the proportion of amylopectin, the higher the GI, because amylopectin, which is made up of large branched-starch molecules, is more easily hydrolyzed in the gut than is the single-strand molecule amylose (van Amelsvoort and Weststrate 1992; Björck et

al. 1994). Thus, rice varieties containing 50-g equivalents of available carbohydrate produce GIs ranging from 27 to 109 (Foster-Powell et al. 2002).

7. Different international agricultural regions. In the Foster-Powell (2002) table, a staple fruit such as orange from five different countries (Denmark, South Africa, Canada, Italy, and USA) provide GI values ranging from 31 to 51.

8. Processing methods (i.e. heat or pressure treatment; mechanical treatment such as the grinding or puffing of grains; cooking treatments such as blanching, thawing, boiling, and microwaving) (Pi-Sunyer, 2002; Guftafsson et al. 1995).

Therefore, while the prior art may suggest the desirability of a low GI food product, having a high carbohydrate content, it does not teach such a food product. Accordingly, the claimed invention in the present case is both novel and inventive.

CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that this application is in condition for allowance and allowance thereof is respectfully requested.

Respectfully submitted,

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Attachment:
1. Declaration of Saul Katz and Valerie Price